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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/446,677	03/24/2000	SVEND BIRKELUND	BIRKELUND=1	2720

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EXAMINER	
SHAHNAN SHAH, KHATOL S	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 03/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/446,677	BIRKELUND ET AL.	
	Examiner	Art Unit	
	Khatol S Shahnan-Shah	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13,15-18,22-25 and 27-33* is/are pending in the application.

4a) Of the above claim(s) *1-4,6,8,9,11,13 and 15-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,7,10,22-25 and 27-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/16/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Supplemental Detailed Action

1. Receipt of the petition filed under 37 CFR 1.181 on 8/30/2004 is acknowledged. Upon reconsideration by the examiner, the petition is moot in light of the supplemental response presented herein regarding the limitation (s) referred in the petition.

2. Applicants' request for reconsideration of the finality of the rejection of the last office action is persuasive and, therefore, the finality of that action mailed 7/23/2004 is withdrawn. The following action is a complete list of objections and rejections of the record.

3. Applicants amendments to the claims received 3/26/2004 are acknowledged. The amendments have been entered. Claims 12, 14, 19-21, 26 and 34-44 have been canceled. Claims 1, 5, 6, 9, 13, 15, 22-25 and 27-33 have been amended.

4. Currently claims 1-11, 13, 15-18, 22-25 and 27-33 are pending.

Claims 5, 7, 10, 22-25 and 27-33 are under examination. Claims 1-4, 6, 8, 9, 11, 13 and 15-18 are withdrawn from consideration as being drawn to non-elected inventions. Upon a complete review of the entire IFW record it is noted that applicants' amendment to the specification, which was received March 26, 2004, in which specification pages 3, 6, 7, 8, 14, 15, 22, 28, 30 and 32 have been amended cannot be entered because the referenced passages do not correspond to the currently filed specification.

Prior Citations of Title 35 Sections

5. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

Information Disclosure Statement

6. Applicants' third Information Disclosure Statement of November 16, 2004 is acknowledged. The reference has been considered by the examiner. See attached PTO form 1449.

Objections/Rejections Withdrawn

7. Objection to claims 27, 28, 29 and 30 made in paragraph 11 of the office action mailed September 26, 2003 is withdrawn in view of applicants' amendments.

8. Objection to claims 34, 37, 38 and 44 made in paragraph 11 of the office action mailed September 26, 2003 is moot in view of applicants' cancellation of said claims.

9. Rejection of claims 26, 43 and 44 made in paragraph 13 of the office action mailed September 26, 2003 is moot in view of applicants' cancellation of said claims.

10. Rejection of claims 19-21, 26 and 34- 44 made in paragraph 14 of the office action mailed September 26, 2003 is moot in view of applicants' cancellation of said claims.

11. Rejection of claims 5, 7 and 10 under 35 USC § 112 First Paragraph, made in paragraph 12 of the office action mailed June 3, 2002 is withdrawn in view of applicants' declaration and amendments.

12. Rejection of claims 5, 7, 10, 22-25 and 27-33 under 35 U.S.C. 112, first paragraph, in regard to **new matter** made in paragraph 14 of the office action mailed

September 26, 2003 is withdrawn in view of applicants' declaration and amendments.

Objections/Rejections Maintained

13. Objection to specification in regard to sequence identifiers, made in paragraph 9 of the office action mailed September 26, 2003 is maintained because applicants' amendments filed 3/26/2004 cannot be entered as explained in paragraph 3 above.

14. Objection to specification, made in paragraph 10 of the office action mailed September 26, 2003 is maintained because applicants' amendments filed 3/26/2004 cannot be entered as explained in paragraph 3 above.

15. Rejection of claims 31 and 32 under 35 U.S.C. 112, second paragraph, made in paragraph 12 of the office action mailed September 26, 2003 is maintained. The applicants have not amended the claims. Claims 31 and 32 are still indefinite because they refer to the figures.

See MPEP 2173.05(s) Reference to Figures or Tables
Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." Ex parte Fressola, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993).

16. The rejection of claim 5 under 35 USC § 102(b), made in paragraph 14 of the office action mailed June 03, 2002 is maintained.

The rejection was as stated below:

Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Melgosa et al. (FEMS Microbiology Letters Vol. 112, No. 2, pp. 199-204, September 1993). Prior art already made of record.

Claim 5 as amended is drawn to a protein derived from *Chlamydia pneumoniae* having the amino acid sequence shown in SEQ ID NO: 2 or an isolated peptide or a protein which consists of an amino acid sequence which is a subsequence of at least six amino acids in length and said protein is being free of any other chlamydial proteins.

Melgosa et al. teach a protein derived from *Chlamydia pneumoniae*. Melgosa et al. teach a 98-kDa protein from outer membrane complex of *Chlamydia pneumoniae* (see abstract and page 202). SEQ ID NO: 2 or a subsequence of the claimed protein are inherent in the 98-kDa protein taught by Melgosa et al.

Applicants' arguments filed March 26, 2004 and 8/30/2004 have been fully considered and are not persuasive.

Applicants in a response filed 3/26/2004 argue the claim recites an isolated protein and it is evident that Melgosa et al. in fact failed to isolate any of the recited chlamydial proteins. Applicants further argue that while Melogosa thought he had a single 98-kDa protein he was mistaken.

It is the examiner's position that Melgosa et al. do teach isolated proteins. Melgosa isolated the proteins by extracting of outer membrane proteins from elementary bodies (EBs) and than the proteins were purified, separated by electrophoresis (SDS-page) into a single band see page 200.

The declaration by Svend Birkelund filed 3/26/04 does not overcome this rejection.

The declarant argues that Melgosa et al. do not teach isolated proteins. It is the examiner's position that Melgosa et al. do teach isolated proteins. Melgosa isolated the proteins by extracting of outer membrane proteins from elementary bodies (EBs) and than the purified proteins were separated by electrophoresis (SDS-page) see page 200. The applicants have not defined the term "isolated" in the specification and by the conventional definition used in the art, Melgosa's proteins is considered an "isolated" protein. The declarant argues that Melgosa's 98 kDa protein was a mixture of proteins. It is the examiner's position that this is merely an opinion of the declarant. The declarant has only asserted that Melgosa's isolated band on the gel was a mixture of proteins. The declarant on section 11 of the declaration is arguing that inventors has Purified the many proteins, which are localized in COMC in the 98-kDa band. However, the declarant has not used the band or the protein isolated by the method of Melgosa. Nor has applicants established by presenting extrinsic evidence before the examiner that the isolated protein of Melgosa comprises many different 98 Kda proteins. Declarant reiterates the teachings of the specification of shotgun expression cloning using a polyclonal antibody. Declarant argues that cloning of multiple 98 Kda proteins that binds the antibody establishes that the protein band of the art has multiple and different 98 Kda proteins. This is not persuasive; cloning does not provide evidence that all the cloned proteins were expressed in the microorganism of the prior art, and further does not establish that they were necessarily present in the isolated protein band of the art. Declarant's antibody is not specific and cross-reacts with a number of proteins in the family described in the specification. Use of the antibody; because it is not specific and

cannot distinguish between proteins cannot be used to establish that the isolated protein band of the prior art has multiple 98 Kda proteins present. Applicants have not presented objective extrinsic or intrinsic evidence that the protein band can be further isolated into multiple components using art conventional techniques such as 2-dimensional electrophoresis, western blotting using specific antibodies, isolecteric focusing. As such, declarant reiteration of the teachings of the specification is not persuasive to remove the rejection of the record.

The declarant further argues that they have employed a rather different and inventive approach to isolate the peptides and provides description of how the applicants have produced the claimed product. It is the examiner's position that the manner of production does not convey patentability and the claims are drawn to a product, how this product is produced does not impart any patentable weight on the product.

In regard to the the limitation " free of any other chlamydial protein" it is the examiner's position that the particular gel band taught by Melgosa is free of any other chlamydial protein and the isolated band represents a single protein as the protein claimed by applicants. The applicants have not defined the term "isolated" in the specification and by the conventional definition used in the art, Melgosa's proteins is considered an "isolated" protein for example medical dictionary defines isolated as placed or standing alone; detached; separated from others. Dorland's Medical dictionary define **isolation (**1. the process of isolating, or the state of being

Isolated. 2. the physiologic separation of a part, as by tissue culture or by interposition of inert material. 3. the extraction and purification of a chemical substance of unknown structure from a natural source.

Melgosa isolated the proteins by extracting of outer membrane proteins from elementary bodies (EBs) and than the purified proteins were separated by electrophoresis (SDS-page) see page 200 and the particular gel band taught by Melgosa is free of any other chlamydial protein and the isolated band represents a single protein.

17. The rejection of claim 7 under 35 USC § 102(b), made in paragraph 15 of the office action mailed June 03, 2002 (paper number 22) is maintained.

The rejection was as stated below:

Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by Melgosa et al. (FEMS Microbiology Letters Vol. 112, No. 2, pp. 199-204, September 1993).

Claim 7 is drawn to a kit comprising a protein with the amino acid sequence shown in SEQ ID NO: 2 or a subsequence thereof indented to be used for diagnosis of infection of a mammal with *Chlamydia pneumoniae*. (The examiner views the claimed kit as a product or a composition comprising a protein of *Chlamydia pneumoniae*). It should be noted that the examiner is viewing the limitation "for diagnosis of infection of a mammal with *Chlamydia pneumonia*" as intended use, which carries little patentable weight to the claimed product.

Melgosa et al. teach a product comprising a protein derived from *Chlamydia pneumoniae.* Melgosa et al. teach a 98-kDa protein from outer membrane complex of *Chlamydia pneumoniae* (see abstract) This composition was used for diagnosis of

Chlamydia *pneumoniae* in rabbits (see page 201). SEQ ID NO: 2 or a subsequence of the claimed invention are inherent in the 98-kDa-protein composition taught by Melgosa et al.

Applicants' arguments filed March 26, 2004 and 8/30/2004 have been fully considered and are not persuasive.

Applicants in a response filed 3/26/2004 argue the claim recites an isolated protein and it is evident that Melgosa et al. in fact failed to isolate any of the recited chlamydial proteins. Applicants further argue that while Melogosa thought he had a single 98-kDa protein he was mistaken.

In a request to withdraw finality filed 8/30/2004 applicants further argue that the examiner has ignored to address the limitation " free of any other chlamydial protein" and the examiner must explain how Melgosa would satisfy the claim with the challenged limitation.

It is the examiner's position that Melgosa et al. do teach isolated proteins. Melgosa isolated the proteins by extracting of outer membrane proteins from elementary bodies (EBs) and than the purified proteins were separated by electrophoresis (SDS-page) see page 200.

The declaration by Svend Birkelund filed 3/26/04 does not overcome this rejection. The declarant argues that Melgosa et al. do not teach isolated proteins. It is the examiner's position that Melgosa et al. do teach isolated proteins. Melgosa isolated the proteins by extracting of outer membrane proteins from elementary bodies (EBs) and than the purified proteins were separated by electrophoresis (SDS-page) see page 200.

The applicants have not defined the term "isolated" in the specification and by the conventional definition used in the art, Melgosa's proteins is considered an "isolated" protein. The declarant argues that Melgosa's 98 kDa protein was a mixture of proteins. It is the examiner's position that this is merely an opinion of the declarant. The declarant has only asserted that Melgosa's isolated band on the gel was a mixture of proteins. The declarant on section 11 of the declaration is arguing that inventors has Purified the many proteins, which are localized in COMC in the 98-kDa band. However, the declarant has not used the band or the protein isolated by the method of Melgosa. Nor has applicants established by presenting extrinsic evidence before the examiner that the isolated protein of Melgosa comprises many different 98 Kda proteins. Declarant reiterates the teachings of the specification of shotgun expression cloning using a polyclonal antibody. Declarant argues that cloning of multiple 98 Kda proteins that binds the antibody establishes that the protein band of the art has multiple and different 98 Kda proteins. This is not persuasive; cloning does not provide evidence that all the cloned proteins were expressed in the microorganism of the prior art, and further does not establish that they were necessarily present in the isolated protein band of the art. Declarant's antibody is not specific and cross-reacts with a number of proteins in the family described in the specification. Use of the antibody; because it is not specific and cannot distinguish between proteins cannot be used to establish that the isolated protein band of the prior art has multiple 98 Kda proteins present. Applicants have not presented objective extrinsic or intrinsic evidence that the protein band can be further isolated into multiple components using art conventional techniques such as 2-

dimensional electrophoresis, western blotting using specific antibodies, isolecteric focusing. As such, declarant reiteration of the teachings of the specification is not persuasive to remove the rejection of the record.

The declarant further argues that they have employed a rather different and inventive approach to isolate the peptides and provides description of how the applicants have produced the claimed product. It is the examiner's position that the manner of production does not convey patentability and the claims are drawn to a product, how this product is produced does not impart any patentable weight on the product.

In regard to the the limitation " free of any other chlamydial protein" it is the examiner's position that the particular gel band taught by Melgosa is free of any other chlamydial protein and the isolated band represents a single protein as the protein claimed by applicants. The applicants have not defined the term "isolated" in the specification and by the conventional definition used in the art, Melgosa's proteins is considered an "isolated" protein for example medical dictionary defines isolated as placed or standing alone; detached; separated from others. Dorland's Medical dictionary define isolation (1. the process of isolating, or the state of being Isolated. 2. the physiologic separation of a part, as by tissue culture or by interposition of inert material. 3. the extraction and purification of a chemical substance of unknown structure from a natural source.

Melgosa isolated the proteins by extracting of outer membrane proteins from elementary bodies (EBs) and than the purified proteins were separated by electrophoresis (SDS-page) see page 200 and the particular gel band taught by Melgosa is free of any other chlamydial protein and the isolated band

represents a single protein.

18. The rejection of claim 10 under 35 USC § 102(b), made in paragraph 16 of the office action mailed June 03, 2002 (paper number 22) is maintained.

The rejection was as stated below:

Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Melgosa et al. (FEMS Microbiology Letters Vol. 112, No. 2, pp. 199-204, September 1993).

Claim 10 is drawn to a composition comprising a protein with the amino acid sequence shown in SEQ ID NO: 2 or a subsequence thereof indented to be used for immunizing a mammal against *Chlamydia pneumoniae.* It should be noted that the examiner is viewing the limitation "for immunizing a mammal against *Chlamydia pneumoniae*" as intended use, which carries little patentable weight to the claimed product.

Melgosa et al. teach a composition comprising a protein derived from *Chlamydia pneumoniae.* Melgosa et al. teach a composition of 98-kDa protein from outer membrane complex of *Chlamydia pneumoniae* (see abstract) This composition was used to immunize rabbits (see page 200). SEQ ID NO: 2 or a subsequence of the claimed invention are inherent in the 98-kDa-protein composition taught by Melgosa et al.

Applicants' arguments filed March 26, 2004 and 8/30/2004 have been fully considered and are not persuasive.

Applicants in a response filed 3/26/2004 argue the claim recites an isolated protein

and it is evident that Melgosa et al. in fact failed to isolate any of the recited chlamydial proteins.

Applicants further argue that while Melogosa thought he had a single 98-kDa protein he was mistaken.

In a request to withdraw finality filed 8/30/2004 applicants further argue that the examiner has ignored to address the limitation " free of any other chlamydial protein" and the examiner must explain how Melgosa would satisfy the claim with the challenged limitation

It is the examiner's position that Melgosa et al. do teach isolated proteins. Melgosa isolated the proteins by extracting of outer membrane proteins from elementary bodies (EBs) and than the purified proteins were separated by electrophoresis (SDS-page) see page 200.

The declaration by Svend Birkelund filed 3/26/04 does not overcome this rejection. The declarant argues that Melgosa et al. do not teach isolated proteins. It is the examiner's position that Melgosa et al. do teach isolated proteins. Melgosa isolated the proteins by extracting of outer membrane proteins from elementary bodies (EBs) and than the purified proteins were separated by electrophoresis (SDS-page) see page 200. The applicants have not defined the term "isolated" in the specification and by the conventional definition used in the art, Melgosa's proteins is considered an "isolated" protein. The declarant argues that Melgosa's 98 kDa protein was a mixture of proteins. It is the examiner's position that this is merely an opinion of the declarant. The declarant has only asserted that Melgosa's isolated band on the gel was a mixture of

proteins. The declarant on section 11 of the declaration is arguing that inventors has Purified the many proteins, which are localized in COMC in the 98-kDa band. However, the declarant has not used the band or the protein isolated by the method of Melgosa. Nor has applicants established by presenting extrinsic evidence before the examiner that the isolated protein of Melgosa comprises many different 98 Kda proteins. Declarant reiterates the teachings of the specification of shotgun expression cloning using a polyclonal antibody. Declarant argues that cloning of multiple 98 Kda proteins that binds the antibody establishes that the protein band of the art has multiple and different 98 Kda proteins. This is not persuasive; cloning does not provide evidence that all the cloned proteins were expressed in the microorganism of the prior art, and further does not establish that they were necessarily present in the isolated protein band of the art. Declarant's antibody is not specific and cross-reacts with a number of proteins in the family described in the specification. Use of the antibody; because it is not specific and cannot distinguish between proteins cannot be used to establish that the isolated protein band of the prior art has multiple 98 Kda proteins present. Applicants have not presented objective extrinsic or intrinsic evidence that the protein band can be further isolated into multiple components using art conventional techniques such as 2-dimensional electrophoresis, western blotting using specific antibodies, isolecteric focusing. As such, declarant reiteration of the teachings of the specification is not persuasive to remove the rejection of the record.

The declarant further argues that they have employed a rather different and inventive approach to isolate the peptides and provides description of how

the applicants have produced the claimed product. It is the examiner's position that the manner of production does not convey patentability and the claims are drawn to a product, how this product is produced does not impart any patentable weight on the product.

In regard to the the limitation " free of any other chlamydial protein" it is the examiner's position that the particular gel band taught by Melgosa is free of any other chlamydial protein and the isolated band represents a single protein as the protein claimed by applicants. The applicants have not defined the term "isolated" in the specification and by the conventional definition used in the art, Melgosa's proteins is considered an "isolated" protein for example medical dictionary defines isolated as placed or standing alone; detached; separated from others. Dorland's Medical dictionary define isolation (1. the process of isolating, or the state of being Isolated. 2. the physiologic separation of a part, as by tissue culture or by interposition of inert material. 3. the extraction and purification of a chemical substance of unknown structure from a natural source.

Melgosa isolated the proteins by extracting of outer membrane proteins from elementary bodies (EBs) and than the purified proteins were separated by electrophoresis (SDS-page) see page 200 and the particular gel band taught by Melgosa is free of any other chlamydial protein and the isolated band represents a single protein.

New Objections / Rejections

19. The disclosure is objected to because of the following informalities: Specification Page 27, line 30 there is a misspelled word " contics". Appropriate correction is required.

20. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification lack antecedent basis for " A non naturally occurring protein" recited in claim 5.

Claim Rejections - 35 USC § 112

21. Claims 5, 7, 10, 22-25 and 27-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

Amended claim 5 now includes the newly added limitation " A non naturally occurring protein". However, there appears to be no antecedal basis or descriptive support in the instant specification for this added limitation. Applicants are respectfully requested to point out to the proper descriptive support in specific part (s) of the disclosure as filed, for the newly added limitation, or to remove the new matter from the claims.

22. Claims 5, 7, 10, 22-25 and 27-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time

the application was filed, had possession of the claimed invention. **This is a written description rejection.**

Claim 5 recites, " said subsequence comprising at least one T cell epitope of at least one of said proteins". The specification page 17, lines 30-31 recites " it is envisioned that particularly interesting and immunogenic epitopes will be found in connection with the proteins of the invention.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a recitation of a subsequence comprising at least one T-cell epitope of at least one of said isolated proteins. There is no description of these subsequences or the T-cell epitopes in the specification as filed. Further, there is no identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states, "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The

specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the full sequences isolated from *Chlamydia pneumoniae* and fails to describe any T-cell epitopes or subsequences comprising at least 6 consecutive amino acids.

Therefore, only isolated polypeptides comprising the amino acid sequences set forth in SEQ ID NOS: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22 and 24 meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

23. Claims 5, 7, 10, 22-25 and 27-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 5 and every claim dependent thereon such as claims 7, 10, 22-25 and 27-30 are indefinite because claim 5 recites the limitation " A non naturally occurring protein". It is not clear what does this limitation encompass.

Claim 5 recites the phrase " an amino acid sequence which is a subsequence, at least 6 amino acid in length". It is not clear that this sequence of a subsequence of which sequence or protein.

Claim 5 recites in part (ii) an isolated or non naturally occurring peptide or protein and later in the same section recites said isolated proteins in plural form. It is not clear what the applicants intend in said recitations.

Claim 5 recites the limitation "said isolated proteins". There is insufficient antecedent basis for this limitation in the claim because claim 5 recites two different proteins in part (i) and (ii). It is not clear which protein the applicants are referring to.

Claims 27-33 recites the limitation "The protein or peptide of claim 5". There is insufficient antecedent basis for this limitation in the claims because claim 5 rceites two different proteins in part (i) and (ii). It is not clear which protein the applicants are referring to.

24. Claims 27-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Melgosa et al. (FEMS Microbiology Letters Vol. 112, No. 2, pp. 199-204, September 1993). Prior art already made of record.

Claims 27-33 which dependent from 5 are drawn to fragments or motifs of a protein derived from *Chlamydia pneumoniae* having the amino acid sequence shown in SEQ ID NO: 2 or an isolated peptide or a protein which consists of an amino acid sequence which is a subsequence of at least six amino acids in length and said protein is being free of any other chlamydial proteins.

Melgosa et al. teach a protein derived from *Chlamydia pneumoniae*. Melgosa et al. teach a 98-kDa protein from outer membrane complex of *Chlamydia pneumoniae* (see abstract and page 202). SEQ ID NO: 2, a subsequence or motifs of the claimed protein are inherent in the 98-kDa protein taught by Melgosa et al.

Conclusion

25. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on 7:30am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (571)-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645

March 4, 2005

PATRICIA A. DUFFY
PRIMARY EXAMINER